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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/668,883	09/23/2003	John Paul Maye	50557-11	3592
21874	7590	01/27/2006		
EDWARDS & ANGELL, LLP P.O. BOX 55874 BOSTON, MA 02205			EXAMINER FLOOD, MICHELE C	
			ART UNIT	PAPER NUMBER
			1655	

DATE MAILED: 01/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/668,883

Applicant(s)

MAYE, JOHN PAUL

Examiner

Michele Flood

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 October 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6-12 and 17-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6-12 and 17-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>10/28/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 28, 2005 has been entered.

The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office action.

Claims 6-12 and 17-23 are under examination.

Response to Arguments

Claim Rejections - 35 USC § 103

Claims 6-12 and 17-23 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Krishna et al. (U), as evidenced by Newmark et al. (*A), Muller (N), and Haas et al. (*C) in view of Hunter et al. (*B) and Johnson et al. (O). The rejection stands for the reasons set forth in the previous Office action and for the reasons set forth below.

Applicant's arguments have been fully considered but they are not deemed persuasive because the cited references provide the suggestions and motivation to the claimed invention.

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In response to Applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

Applicant's main argument is directed to the idea that Krishna teaches away from the instantly claimed invention because the referenced spent hop composition H₃ contained a number of ingredients besides the hop acids contained therein. While Applicant points out that Krishna suggests the belief for the toxicity and interferences of factors, such as isohumulones, with the utilization of energy in ruminant animals and while Applicant reasonably argues that Krishna failed to identify the agent responsible for the reduction of methane by the spent hops compositions, the data reported by the experiments conducted by Krishna clearly indicates the nutritive value and beneficial functional effects of the different spent hops compositions when the spent hops preparations were incubated in a rumen simulator. The data disclosed by Krishna investigation clearly teaches the antimethanogenic activity of spent hop composition H₃, which comprised the claimed designated ingredients of hop acid. Therefore, the primary reference of Krishna was relied upon because Krishna discloses the results of two long-term experiments, which studied the effects of diets consisting

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of preparation of spent hops and apple pomace in simulated rumen fermentation.

For instance, Krishna teaches, "The spent hops preparations were: (H1) hops extracted with CH_2Cl_2 , (H2) hops extracted with hot water, (H3) treatment with supercritical CO_2 at 45-50° up to 400 atm pressure, (H4)-mechanical sifting of hop powder at -35°. The diet containing H3 gave markedly lower CH_4 output, a slight increase in propionic acid, and a marked decrease in HOAc per unit dry matter digested. The amounts of hexose used and the recovery of H_2 were low in H3-complete diet. Addition of apple pomace to basal diets of hay, H3, or their mixture only resulted in a marked overall decrease in N and dry matter digestibility. Preparation H2 had highest lignin and lowest degradable cell wall contents (resistant to 3% alkali and NH_3) and, in Rusitec, had the lowest digestible N and dry matter. Spent hop preparations H1 and H4 appear to have the greatest potential as animal feed components. A significant increase in total volatile fatty acids and CH_4 production was observed when any spent hop preparation was incubated in separate bags rather than in mixtures with other components." Because Krishna did not expressly teach that the spent hops used in the experimental studies comprised the instantly claimed ingredients of hop acids, the secondary references of Newmark, Muller and Haas were relied upon to establish that the instantly claimed ingredients of hop acids were inherent to the spent hops extracts taught by Krishna. Firstly, Newmark taught that a supercritical carbon dioxide extract of hops comprises alpha acids, *i.e.*, humulones; and, beta acids, *i.e.*, lupulones, in Column 6, lines 27-31. Secondly, in Column 1, lines 43-54, Muller taught that alpha acids, such as humulones, and

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beta acids, such as lupulones, are inherent components of spent hops. Muller further taught a process for obtaining lupulones or hulupones from lupulones from hop extracts by treatment with supercritical carbon dioxide under a reduced pressure. Thirdly, Hass also taught that hop resins or hop acids (both alpha acids and beta acids) can be obtained from the hop plant by supercritical critical carbon dioxide treatment, in Column 1, lines 1-41. Haas further taught that treating hop acid extracts with carbon dioxide greatly improves the killing activity of alpha acids, e.g., humulone, isoalpha acids, and tetraisoalpha acids, and beta acids, e.g., xanthohumol for protozoa.

With regard to Applicant arguments that the references of Newmark, Muller, Hass and Johnson constitute non-analogous art since the referenced prior art relate to 'hop extracts', which are distinct and different from 'spent hops', the Office respectfully disagrees. For instance, although Krishna refers to the compositions as 'spent hops', Krishna clearly teaches the method of making by which the 'spent hops' compositions used in his investigation were made. See Abstract, wherein Krishna clearly teaches that the method used in the making of the investigated spent hops H₃ composition is one and the same method of making the compositions taught by each of Newmark, Muller, Hass and Johnson. Also **see Table 2** and page 112, lines 6-11. Thus, the H3 spent hops, as well as H1, H2 and H4 spent hops, taught by Krishna are still deemed to inherently comprise the instantly claimed alpha acids and beta acids. Moreover, the Office notes that Applicant readily admits that the introduction of low levels of the claim-designated ingredients into an artificial rumen provided the functional effect for

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increase in propionate levels, wherein such an increase in propionate concentration is significant since propionate makes up about 50% of the carbon source used by animals for growth, on page 3, lines 17-21, of the present specification. Furthermore, Applicant readily admits that low levels of hop acids into an artificial rumen caused a reduction of butyrate which means a reduction in methane with a result-variable of reduction of bacteria content in livestock fermentation. Note that Krishna expressly teaches that the introduction of effective amounts of the spent hops into an artificial rumen, especially H3, increased propionate levels, and decreased both butyric acid and methane output.

As set forth above, the objective of the experimental studies reported by Krishna investigated the nutritive value of various preparations of spent hops and the effects of spent hops in simulated rumen fermentation. See page 100, under "*METHODS AND MATERIALS*". Thus, Krishna does not teach a method for increasing food and energy uptake from a livestock feed by livestock comprising administering to the livestock an effective amount of hop acid capable of decreasing the production of unoxidized carbon sources in a digestive system fluid of a livestock and wherein the method hop acid is capable of increasing the level of propionate in the digestive system fluid of the livestock. Thus, the tertiary reference of Hunter was relied upon merely to demonstrate that the administration of a composition known in the art to have the beneficial functional effect of decreasing the production of unoxidized carbon sources in a digestive system fluid of a livestock, and increasing the level of propionate in the digestive

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system fluid would provide the instantly claimed method for increasing food and energy uptake by administration of such a composition to the livestock. Thus, although Applicant argues that one would not combine the teachings of Hunter or be motivated by the teachings of Hunter to arrive at the instantly claimed subject matter, it would have been more than obvious to one of ordinary skill in the art to modify the *in vitro* method taught by Krishna to an *in vivo* method for administering the spent hops taught by Krishna to livestock to provide the instantly claimed invention because Krishna taught that the administration of effective amounts of the livestock feed, especially H3, to a simulated rumen digestion system had the beneficial effect for markedly reducing the production of unoxidized carbon sources, *i.e.*, methane, and an increase in propionic acid. Since Krishna taught that the referenced spent hops extract markedly lowered methane output and increased the production of propionic acid, one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to administer an effective amount of the livestock feed taught by Krishna to a livestock animal to provide the instantly claimed method because at the time the invention was made it was known in the art that a decrease in methane output and an increase in propionic acid production in a digestive system fluid of a livestock indicates a shift in the microbial population of microorganisms normally residing in the rumen of livestock. For instance, in Column 14, lines 22-36, Hunter teaches, "The biologically-active copolymers can also be added to cattle feed to effect a change in the population of microorganisms normally resident in the rumen. Under normal conditions, the

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microorganisms digest the cellulose that is eaten by the cattle to the end-product methane. Methane is essentially unusable by the cattle. By administering the biologically active copolymers of the present invention orally to the cattle, the copolymer differentially affects the rumen population of microorganism resulting in an increase in propionic acid production and a decrease in lactic acid and methane. Cattle are capable of using propionate in their own metabolism thereby increasing the efficiency of food conversion.” While it is true that the method for increasing food and energy uptake from a livestock taught by Hunter is not directed to the administration of the claim-designated hop acid of Applicant’s instantly claimed invention, the reliance upon the teachings of Hunter was introduced merely as evidence that the administration of effective amounts of compositions known in the art to have the beneficial functional effects for decreasing the production of unoxidized carbon sources, such as methane, and increasing the level of propionate in the digestive system, as a result-effective variable in shifting the residence population of microorganisms present in the digestive fluid of an animal, simultaneously provided a method for increasing food and energy uptake from a livestock feed by a livestock ingesting such a composition. Hence, contrary to Applicant’s argument, one of ordinary skill in the art would have indeed looked to the teachings of Hunter to provide the instantly claimed invention because at the time the invention was made, it would have been obvious to one of ordinary skill in the art and one would have been motivated and one would have had a reasonable expectation to replace one

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composition for the other known in the art to have similar functional effects when administered in the feed of a livestock to provide the instantly claimed invention.

With regard to Claim 10 wherein Applicant directs the method of claim 6 to wherein the amount of hop acid is 2 ppm of digestive system fluid, at the time the invention was made, it would have been obvious to one of ordinary skill in the art and one would have been motivated and one would have had a reasonable expectation of success to optimize the amounts of the hop acids administered in the method of treatment taught by Krishna because Krishna teaches that the administration of the instantly claimed ingredients have the beneficial effect for decreasing the production of unoxidized carbon sources and increasing the level of propionate in rumen and suggests using the hop acid extracts as livestock feed. It also would have been obvious to provide the instantly claimed amounts of the spent hops extracts taught by Krishna in the instantly claimed amounts in the digestive system of an animal, and one would have been further motivated and had a reasonable expectation of success to provide the instantly claimed amounts of hop acids in the digestive system of an animal because at the time the invention was made Johnson taught that supercritical carbon dioxide extracts of hops in the claim-designated amounts provide protection against *Clostridium* spp. and that incorporation of upper levels of beta acids to an oral composition is dictated by taste and solubility of a food product, on page 4, lines 12-19.

With regard to Claims 18-23 wherein Applicant directs the method of Claim 6 to wherein the livestock is various claim-designated animals, it would have been obvious to one of ordinary skill in the art and one would have been

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motivated and one would have had a reasonable expectation of success to administer effective amounts of the composition taught by Krishna to any of the claim-designated animals because the choice of the livestock to be administered the compositions taught by Krishna would have been merely a matter of judicious selection to one practicing the invention because at the time the invention was made Krishna provided the motivation and suggestion of utilizing spent hops in animal feeding as a livestock feed, on page 100, lines 9-26; and, because Krishna teaches that the referenced spent hops is rich in crude proteins, has low levels of potentially toxic factors present in hops, and concentrations of readily fermented carbohydrates

Thus, with Krishna providing the motivation to use spent hops comprising alpha acids and beta acids as a livestock feed to decrease the production of unoxidized carbon sources and to increase the level of propionate in the digestive system fluid of an animal, such as a ruminant; and, with each of Krishna, Newmark, Muller and Hass providing evidence that the spent hops taught by Krishna comprise alpha acids and beta acids; and with Hunter suggesting the administration of a composition known in the art to have the beneficial functional effect of decreasing the production of unoxidized carbon sources in a digestive system fluid of a livestock, and increasing the level of propionate in the digestive system fluid would provide the instantly claimed method for increasing food and energy uptake by administration of such a composition to the livestock; and, with Johnson teaching that supercritical carbon dioxide extracts of hops in the claim-designated amounts provide protection

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against *Clostridium* spp. and that incorporation of upper levels of beta acids to an oral composition is dictated by taste and solubility of a food product, it would have it would have been obvious to one of ordinary skill in the art at the time the invention was made to administer the spent hops compositions taught by Krishna to provide a method for increasing food and energy uptake from a livestock feed by livestock because at the time the invention was made the spent hop compositions taught by Krishna were known in the art for the claim-designated functional effects, as suggested by the cited references. As the references indicate that the various proportions and amounts of the ingredients used in the claimed method of treatment are result variables, they would have been routinely optimized by one of ordinary skill in the art in practicing the invention disclosed by each of the references. Therefore, the invention as a whole was clearly *prima facie* obvious in the absence to the contrary.

No claims are allowed.

Conclusion

This is a request for continued examination of applicant's earlier Application No. 10/668,883. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on October 28, 2005 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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* Applicant is advised that the cited U.S. patents and patent application publications are available for download via the Office's PAIR. As an alternate source, all U.S. patents and patent application publications are available on the USPTO web site (www.uspto.gov), from the Office of Public Records and from commercial sources. Should you receive inquiries about the use of the Office's PAIR system, applicants may be referred to the Electronic Business Center (EBC) at <http://www.uspto.gov/ebc/index.html> or 1-866-217-9197.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is 571-272-0964. The examiner can normally be reached on 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.MCF

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


MICHELE FLOOD
PRIMARY EXAMINER

Michele Flood
Primary Examiner
Art Unit 1655

MCF
January 17, 2006